

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CENTRAL DIVISION**

LORI NICHOLSON and
WILLIS WILLIAM NICHOLSON,

Plaintiffs,

vs.

BIOMET, INC.; BIOMET ORTHOPEDICS,
LLC; BIOMET MANUFACTURING
CORP.; AND BIOMET US
RECONSTRUCTION, LLC,

Defendants.

Case No. 18-CV-3057 CJW-KEM

ORAL ARGUMENT REQUESTED

**DEFENDANTS' BRIEF IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT**

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Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56(a), Defendants Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing LLC f/k/a Biomet Manufacturing Corp., and Biomet U.S. Reconstruction, LLC (incorrectly named as Biomet US Reconstruction, LLC) (collectively referred to as “Defendants” or “Biomet”), submit this Brief in Support of their Motion for Summary Judgment.

I. INTRODUCTION

This is a products liability action involving an artificial hip implant. The plaintiffs, Lori Nicholson and William Nicholson (“Plaintiffs”), allege that the hip implant used in Plaintiff Lori Nicholson’s left total hip replacement surgery in July 2007, known as the Biomet M2a Magnum, was defective because Ms. Nicholson suffered injuries, including a lump in her left groin, and had to undergo surgery to replace her left hip implant five years later in 2012. (This replacement surgery is known as “revision” surgery.) Plaintiffs allege that Biomet – as manufacturer of the M2a Magnum – is liable to them for damages under theories of strict products liability for the design and manufacture of an unreasonably dangerous product, strict products liability failure to warn and nonconformance with representations, negligence in design, manufacturing, and warnings, breach of express warranty, breach of the implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, punitive damages, and loss of consortium. The undisputed facts show, however, that none of Plaintiffs’ claims have merit for a number of reasons.

First, Plaintiffs abandoned their manufacturing defect claims during discovery. Because they have identified no manufacturing defect or deficiency in the manufacturing process, all claims based on manufacturing defect should be dismissed as a matter of law.

Second, expert testimony is required in complex medical device cases such as this one, and if the Court grants Biomet's contemporaneously filed motion to exclude and limit the opinions of Plaintiffs' lone retained case-specific expert, Steven E. Naide, M.D., Plaintiffs cannot prove product defect, negligence, or medical causation. All of Plaintiffs' claims necessarily fail for lack of admissible expert testimony.

Third, even if the Court denies Biomet's motion to exclude, Plaintiffs' experts have failed to offer any opinions to support a claim that the M2a Magnum had any defect that caused Plaintiffs' alleged injuries. Plaintiffs' failure to present expert evidence on defect and causation leaves Defendants' experts' testimony that the M2a Magnum did not cause Plaintiffs' injuries unrebutted. Put simply, the only admissible expert evidence – Defendants' evidence – disproves Plaintiffs' case and establishes that the M2a Magnum did not cause Plaintiff Lori Nicholson's need for revision surgery. Instead, Ms. Nicholson's need for revision surgery was caused by aseptic loosening of her acetabular component as a consequence of Ms. Nicholson's history of smoking and the subsequent realization that there had been a small central medial wall crack of her acetabulum after the 2007 implantation.

Fourth, Plaintiffs' warning claims fail by application of the learned intermediary doctrine. The M2a Magnum device's warnings are adequate as a matter of law, and Plaintiffs cannot show that any allegedly inadequate or omitted warnings for the Magnum device caused Ms. Nicholson's implanting surgeon, Dr. Emile Li, to implant the M2a Magnum.

Fifth, Plaintiffs' warranty claims fail because Biomet does not provide warranties for its products, and Plaintiffs have presented no evidence to establish any warranty existed between Biomet and Plaintiffs.

Sixth, Plaintiffs' fraud-based claims and breach of implied warranty of fitness for a particular purpose fail because there is no evidence to support that Ms. Nicholson or her surgeon relied on Biomet's package insert or advertising to select the M2a Magnum for use in her left total hip replacement.

Seventh, Iowa does not recognize an independent claim for strict liability product defect—nonconformance with representations.

Eighth, punitive damages are not an independent cause of action under Iowa law, and Plaintiffs cannot otherwise meet the high standard for an award of punitive damages.

Finally, Plaintiff William Nicholson's derivative loss of consortium claim necessarily fails because his spouse, Ms. Nicholson, has no valid claims.

II. UNDISPUTED FACTS¹

A. Plaintiff Lori Nicholson's medical history and left hip replacement surgery

Plaintiff Lori Nicholson has a long history of left hip pain. Ms. Nicholson's hip pain gradually increased from 2002 through 2005. SUMF ¶¶ 1–8. In 2003, she submitted her first application for Social Security Disability for osteoarthritis. SUMF ¶ 5. On October 27, 2005, she began seeking treatment from orthopedic surgeon, Dr. Emile Li. SUMF ¶ 8. Ms. Nicholson was only 43 years old at the time. SUMF ¶ 9. Dr. Li reviewed x-rays of Ms. Nicholson's left hip that showed severe degenerative changes to her left hip to the extent that it "was essentially grinding bone on bone." SUMF ¶¶ 10–11. By November 18, 2005, Dr. Li also noted that Ms. Nicholson had a leg length discrepancy, which was causing her to limp. SUMF ¶ 12. Even though Ms. Nicholson's pain was severe, Dr. Li advised Ms. Nicholson to pursue conservative treatment.

¹ Defendants summarize the material, undisputed facts here for this Court's convenience. However, the complete recitation of facts material to Defendants' Motion for Summary Judgment are set forth in their Statement of Undisputed Material Facts ("SUMF"), filed contemporaneously with this Brief and incorporated here by this reference.

SUMF ¶¶ 14–16. Dr. Li recommended conservative treatment because Ms. Nicholson was only 43 years old, and all hip replacements have a finite life. SUMF ¶¶ 9, 16. Ms. Nicholson received hip injections and took anti-inflammatories to treat her pain. SUMF ¶¶ 14–15.

Eventually, the injections stopped providing Ms. Nicholson with relief. SUMF ¶¶ 14, 17. In March 2006, Dr. Li suggested that Ms. Nicholson begin considering a total hip arthroplasty using an uncemented metal on metal device. SUMF ¶ 17.

By May 19, 2006, Dr. Li began discussing with Ms. Nicholson the risks and benefits of total hip arthroplasty², including leg length inequality, dislocation, infection, the need for 2-stage reimplantation, DVT formation, blood transfusions, femur fracture, sciatic nerve palsy, perioperative medical complications, and the possible need for revision due to loosening. SUMF ¶ 22. Ms. Nicholson trusted Dr. Li to choose the appropriate device for her surgery. SUMF ¶¶ 26, 28. Dr. Li informed Ms. Nicholson that he would use a Biomet M2a Magnum metal-on-metal uncemented hip implant for her surgery. SUMF ¶ 25. Ms. Nicholson did not do any research on the M2a Magnum. SUMF ¶ 27.

As Ms. Nicholson considered whether to move forward with surgery, her pain continued to get worse. SUMF ¶¶ 44–46. On July 25, 2006, Ms. Nicholson’s osteoarthritis in her left hip was so severe that Dr. Li certified that she was disabled and would be unable to work for at least one year. SUMF ¶ 44. On September 27, 2006, Ms. Nicholson filled out a form claiming she had been disabled since 2003 due to severe osteoarthritis in her left hip. SUMF ¶ 46. Ms. Nicholson

² The hip is a “ball and socket” joint that is held together by ligaments. The ball is called the femoral head and is located at the top of the femur (or thigh bone). The socket is called the acetabulum and is part of the pelvis. The femoral head fits into the acetabulum to create the hip joint, which is normally held tightly in place by the surrounding bands of tissue (ligaments) that form the joint capsule. A layer of firm, rubbery material called cartilage cushions the surface of the end of the bones in the hip, helping the ball to rotate easily in the socket. Total hip arthroplasty (“THA”) involves removing a diseased hip joint and replacing it with a prosthetic joint. A THA implant has three basic parts: 1. the stem, which fits into the patient’s femur; 2. the ball, which replaces the spherical head of the patient’s femur; and 3. the cup, which replaces the hip socket (acetabulum). A taper insert is sometimes used to connect the stem to the ball. A taper insert was used with Ms. Nicholson’s Magnum device.

scheduled her left total hip arthroplasty on June 15, 2007. SUMF ¶ 47. When she scheduled her surgery, Dr. Li explained that he would not be able to fully fix her leg length discrepancy during the procedure. SUMF ¶ 23.

On July 10, 2007, Dr. Li performed a total hip arthroplasty on Ms. Nicholson. SUMF ¶ 50. Dr. Li used a Biomet M2a Magnum hip system for Ms. Nicholson's total left hip arthroplasty. SUMF ¶ 50. Dr. Li's postoperative diagnosis was osteoarthritis left hip, severe. SUMF ¶ 51. Ms. Nicholson was 45 years old at the time of her left hip replacement. SUMF ¶ 48.

B. The Biomet M2a Magnum

The Biomet M2a Magnum is a large head metal articulation metal-on-metal hip replacement. The Biomet M2a Magnum contains three components, a femoral head, a taper insert, and an acetabular cup. SUMF ¶ 18. The head and acetabular cup components are made from cobalt chrome molybdenum (CoCrMo) alloy. SUMF ¶ 19. The taper insert is made of a titanium alloy. SUMF ¶ 20. The acetabular cup, which is seated in the hip, is treated with a titanium Porous Plasma Spray. SUMF ¶ 21. A picture of the M2a is set forth below in Figure 1.

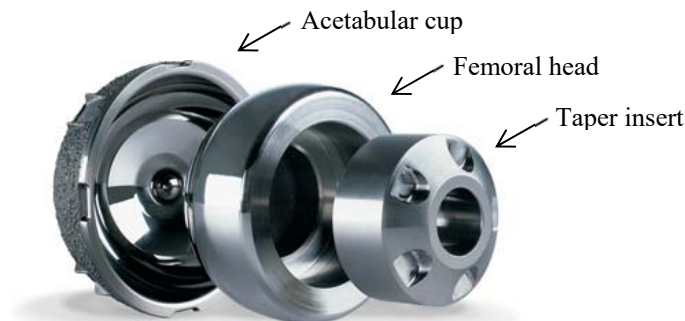


Figure 1. M2a Hip Replacement

Biomet included a package insert or Instructions for Use (“IFU”) with its M2a products, including Ms. Nicholson's M2a Magnum prosthesis. *See generally* Exs. G-I. The IFU for Ms. Nicholson's Magnum identified several possible adverse effects and risks, including:

1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions in various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and dislocation from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. A low incidence of metal hypersensitivity has been reported with failed metal on metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.
4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
10. Fretting and crevice corrosion may occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
15. Elevated metal ion levels have been reported with metal on metal articulating surfaces. Although mechanical testing demonstrates that metal on metal articulating surfaces generate a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

See SUMF ¶¶ 37–39, 110–11. Dr. Li does not recall whether he read Ms. Nicholson’s M2a Magnum’s IFU prior to her implantation surgery. *See* SUMF ¶ 134.

C. Ms. Nicholson’s course and revision surgery

Within six weeks of her July 2007 left hip replacement, Ms. Nicholson reported that her pain was gone. SUMF ¶ 54. On September 11, 2007, Ms. Nicholson was fitted with a shoe lift. SUMF ¶ 55. At her November 26, 2007 follow-up appointment with Dr. Li, an x-ray showed a small central medial wall crack in the acetabulum of her left hip. SUMF ¶ 56. However, there was no change in the original alignment of the acetabular component. SUMF ¶ 57. By 2008, Ms. Nicholson was experiencing no hip pain or physical limitations from her hip, and her leg lengths felt equal. SUMF ¶ 60. Ms. Nicholson returned to her daily activities. SUMF ¶¶ 59–60, 63.

In 2009, Ms. Nicholson returned to work as a cook in the school system. SUMF ¶ 59. Ms. Nicholson was able to complete household chores, including yard work like using a push mower for 30 to 40 minutes. SUMF ¶ 63.

On November 9, 2011, Ms. Nicholson again sought treatment for her left hip from Dr. Li. SUMF ¶ 61. Ms. Nicholson reported that she had begun experiencing pain when she went back to work in late summer 2011. SUMF ¶ 62. Ms. Nicholson described a catching or clicking in her left hip. SUMF ¶ 66. Ms. Nicholson told Dr. Li that she had developed a small lump in her left groin that fluctuated in size. SUMF ¶ 65.

Dr. Li also ordered metal ion testing on December 22, 2011, which showed that Ms. Nicholson had an elevated chromium serum level of 1.7 ng/mL. SUMF ¶ 67. Ms. Nicholson's cobalt level was within normal limits. SUMF ¶¶ 67, 132. Dr. Li explained that the metal ion levels were high, but not dangerous to Ms. Nicholson. SUMF ¶ 68.

On May 7, 2012, Dr. Li ordered x-rays, which showed that she had a case of aseptic loosening of her M2a Magnum acetabular component (the cup). SUMF ¶¶ 69–71. Her cup had migrated into a more vertical position, which made it more susceptible to wear. SUMF ¶ 73. Dr. Li concluded that there had been unsuccessful bony ingrowth of the acetabular component. SUMF ¶ 72. Simply put, Ms. Nicholson's acetabular cup was loose and lacked bony ingrowth. SUMF ¶¶ 69, 72.

Dr. Li recommended that Ms. Nicholson have a revision surgery to address the loose acetabular component. SUMF ¶ 72. In preparation for the revision surgery, Dr. Li ordered some imaging of the lump in Ms. Nicholson's groin. SUMF ¶ 75. On June 5, 2012, Ms. Nicholson had an ultrasound, which showed the lump in her groin was a simple left inguinal cyst. SUMF ¶ 75.

On June 19, 2012, Dr. Li performed a revision surgery of Ms. Nicholson's left hip. SUMF ¶ 76. The revision was not difficult, and there were no intraoperative complications. SUMF ¶ 84. Dr. Li did not observe any tissue destruction or bone loss. SUMF ¶ 82. He did not find any metallosis in Ms. Nicholson's tissues. SUMF ¶ 81. Dr. Li did encounter and decompress a fluid-filled cyst. SUMF ¶ 79. Dr. Li's postoperative diagnosis was "loose acetabular component status post left total hip." SUMF ¶ 77.

On July 27, 2012, Ms. Nicholson returned to Dr. Li, reporting that her cyst had not gone away after the revision surgery. SUMF ¶ 85. Further work up showed that the lump post-revision surgery was a hernia. SUMF ¶ 86. On December 17, 2012, Ms. Nicholson had a hernia repair with Dr. Miegge. SUMF ¶ 86. Ms. Nicholson no longer has a lump in her groin. SUMF ¶ 90. No physician has related the hernia repair to Ms. Nicholson's Biomet M2a Magnum. SUMF ¶ 88.

By the date of her deposition in July 2016, Ms. Nicholson was able to return to her pre-revision activity level. SUMF ¶ 90. She testified that she does not claim to be suffering from any ongoing health issues that are related to her Biomet M2a Magnum implant. SUMF ¶ 90. She has returned to work full time and has started a new job at UnityPoint Health. SUMF ¶¶ 90-91.

D. Plaintiffs' Complaint

On April 25, 2013, Plaintiffs Lori Nicholson and Willis William Nicholson filed their Complaint against Biomet alleging various products liability claims regarding Ms. Nicholson's Biomet M2a Magnum hip implant: 1) Strict Products Liability- Manufacturing Defect, 2) Strict Products Liability-Design Defect, 3) Strict Products Liability-Defect Due to Nonconformance with Representations, 4) Strict Products Liability-Failure to Warn, 5) Negligence, 6) Breach of Express Warranty, 7) Breach of Implied Warranty of Merchantability, 8) Breach of Implied Warranty of Fitness for a Particular Purpose, 9) Negligent Misrepresentation, 10) Fraudulent Misrepresentation, 11) Fraudulent Concealment, 12) Punitive Damages, and 13) Loss of

Consortium of Willis William Nicholson. *See generally*, Doc. 1, Compl. Central to all of Plaintiffs’ products liability causes of action against Biomet is their claim that Ms. Nicholson’s M2a Magnum acetabular cup “loosened, causing increased strain on the acetabulum consistent with increased ionic metal-on-metal wear contributing to a pseudo cyst,” and that Ms. Nicholson’s “chromium levels were 6 times that of the normal rate,” requiring her to undergo revision surgery on June 19, 2012. *See* Doc. 1, Compl., at ¶¶ 29–30. In sum, Plaintiffs claim that they sustained injuries because Ms. Nicholson’s hip implant loosened due to loss of bone fixation and/or loosening of her cup due to elevated metal ion levels.

E. Plaintiffs’ Notice of Serving Expert Disclosures

On June 3, 2019, Plaintiffs filed “Plaintiff[s]’ Notice of Serving Expert Disclosures Pursuant to Fed. R. Civ. P 26” designating Steven N. Naide, M.D. as their lone retained case-specific expert on issues specific to Ms. Nicholson and served Dr. Naide’s case-specific expert report with respect to Ms. Nicholson. SUMF ¶ 93. They also designated Mari Truman, M.S. P.E., George S. Kantor, M.D., and Francis H. Gannon, M.D. as their retained common-issue experts. SUMF ¶ 103. These retained common-issue experts submitted their common-issue reports in the M2a MDL, *In re: Biomet M2a Magnum Hip Implant Products Liability Litigation*, 3:12-MD-2391, and none of these retained common-issue experts offer any case-specific opinions concerning the medical cause of Ms. Nicholson’s alleged injuries and need for revision surgery. SUMF ¶ 109. Finally, Plaintiffs designated Ms. Nicholson’s implanting and revising surgeon – Dr. Emile C. Li. – as their lone non-retained expert.

III. ARGUMENT

A. The standard for summary judgment.

Summary judgment is “designed to secure the just, speedy and inexpensive determination of every action.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (internal citations and

quotations omitted); see *Torgerson v. City of Rochester*, 643 F.3d 1031, 1043 (8th Cir. 2011). Summary judgment is correctly granted where there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). “[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of material fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986) (emphasis in original). “Evidence that only provides ‘some metaphysical doubt as to the material facts,’ or evidence that is ‘merely colorable’ or ‘not significantly probative,’ does not make an issue of material fact genuine.” *Merfeld v. Dometic Corp.*, 306 F. Supp. 3d 1070, 1075 (N.D. Iowa 2018), *aff’d*, 940 F.3d 1017 (8th Cir. 2019) (quoting first *Matsushita Elec. Indus. Co.*, 475 U.S. at 586–87, quoting second *Anderson*, 477 U.S. at 249–50). The function of summary judgment is to “pierce the pleadings and to assess the proof in order to see whether there is a genuine issue for trial.” *Matsushita Elec. Indus. Co.*, 475 U.S. at 587 (quoting Advisory Committee Note to 1963 Amendment to Fed. R. Civ. P. 56(e)).

As the nonmoving party, Plaintiffs is only entitled to those inferences reasonably drawn from the facts. See, e.g., *Johnson v. Ready Mixed Concrete Co.*, 424 F.3d 806, 810 (8th Cir. 2005). The court “do[es] not weigh the evidence or attempt to determine the credibility of the witnesses.” *Merfeld*, 306 F. Supp. 3d at 1076 (quoting *Kammueler v. Loomis, Fargo & Co.*, 383 F.3d 779, 784 (8th Cir. 2004)). Instead, the court’s “function is to determine whether a dispute about a material fact is genuine.” *Id.* (quoting *Quick v. Donaldson Co.*, 90 F.3d 1372, 1376–77 (8th Cir. 1996)).

As the moving party, Biomet is required to “inform[] the district court of the basis for its motion and identify[] those portions of the record which show a lack of genuine issue.” *Hartnagel*

v. Norman, 953 F.2d 394, 395 (8th Cir. 1992). Once the moving party has carried its burden, “the nonmoving party has an affirmative burden to go beyond the pleadings and by depositions, affidavits, or otherwise designate ‘specific facts showing that there is a genuine issue for trial.’” *Benedict v. Zimmer, Inc.*, 405 F. Supp. 2d 1026, 1031 (N.D. Iowa 2005) (quoting Fed. R. Civ. P. 56(e)). In fact, the party opposing summary judgment must show that there is sufficient evidence to support a jury verdict in its favor. *Anderson*, 477 U.S. at 249. Under these well-established principles, Biomet is entitled to summary judgment as a matter of law.

B. Biomet is entitled to summary judgment on all manufacturing defect-based claims because Plaintiffs have admitted they do not contend there was a manufacturing defect or deficiency in Ms. Nicholson’s M2a Magnum.

Plaintiffs’ claims alleging deficiencies in the manufacturing of the M2a Magnum should be dismissed because those claims have been abandoned by Plaintiffs during discovery. To establish a manufacturing defect under Iowa law, a plaintiff must prove that “the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.” *Wright v. Brooke Grp., Ltd.*, 652 N.W.2d 159, 168 (Iowa 2002) (quoting Restatement (Third) of Torts: Prods. Liab. § 2, at 14). Thus, a manufacturing defect cannot occur when the products used by the plaintiff were in the condition intended by the manufacturer. *Id.* at 178; *see also Nationwide Agribusiness Ins. Co. v. SMA Elevator Const. Inc.*, 816 F. Supp. 2d 631, 663 (N.D. Iowa 2011). Further, under Iowa law manufacturing defect and implied warranty of merchantability claims are duplicative and may not be pursued together in the same case. *See Depositors Ins. Co. v. Wal-Mart Stores, Inc.*, 506 F.3d 1092, 1095 (8th Cir. 2007) (citing Restatement (Third) of Torts: Prods. Liab. § 2(a) cmt. n).

Here, Plaintiffs have abandoned their claims premised on defects or deficiencies in the manufacturing of Ms. Nicholson’s M2a device. They have failed to present any evidence to support that the M2a Magnum was not in the condition intended by Biomet. SUMF ¶¶ 92–93.

Further, Plaintiffs’ retained case-specific expert Steven E. Naide, M.D. did not inspect the device or contend that he had any opinions as to whether there was a manufacturing defect in Ms. Nicholson’s device. SUMF ¶¶ 93, 97. Similarly, Plaintiffs’ common-issue experts did not inspect Ms. Nicholson’s device, and they offer no opinions specific to Ms. Nicholson or her device. SUMF ¶ 109.

In light of Plaintiffs’ admission, all of Plaintiffs’ claims premised on manufacturing defect should be dismissed as a matter of law. *See* Doc. 1, ¶¶ 34-39 (Count 1), ¶¶ 83-90 (Count 5-as it relates to manufacturing); ¶¶ 97-103 (Count 7).

C. Biomet is entitled to summary judgment on all of Plaintiffs’ claims based on the exclusion of Plaintiff’s case-specific expert Dr. Naide.

As the Court is aware, contemporaneously with this summary judgment motion, Biomet has filed a *Daubert* motion seeking to exclude the proposed trial testimony of Plaintiffs’ only case-specific expert, Steven E. Naide, M.D. Biomet is entitled to summary judgment as to all claims against it based on the exclusion of those Dr. Naide’s testimony.

Plaintiffs’ claims about Ms. Nicholson’s M2a Magnum device involve complex medical and scientific issues which require expert testimony to establish product defect and negligence (design, manufacturing, or warnings) and medical causation (design, manufacturing, or warnings). *See Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 707 (8th Cir. 2018) (“[U]nder Iowa law, ‘[d]ue to its complex and scientific nature, medical causation almost always requires expert testimony.’” (quoting *Anderson v. Bristol, Inc.*, 936 F. Supp. 2d 1039, 1067 (S.D. Iowa 2013))). With the exclusion of their expert’s key opinions, all of Plaintiffs’ claims fail as a matter of law.

Medical device product defect cases almost categorically require case-specific expert testimony because they raise causation issues that are beyond the knowledge of a layperson. *See*

Benedict, 405 F. Supp. 2d at 1032–33. Expert testimony is required to prove a design defect case when the ultimate decision turns on “technical, scientific issues which cannot be fully understood by the average juror without some expert assistance.” *Cummings v. Deere & Co.*, 589 F. Supp. 2d 1108, 1118 (S.D. Iowa 2008) (quoting *Benedict*, 405 F. Supp. 2d at 1032). Courts have held that a wide variety of product defect claims require expert testimony to prove causation under Iowa law, including an allegedly defective hip implant case. *Benedict*, 405 F. Supp. 2d 1026. When a plaintiff’s case raises “sophisticated issues of technological possibility,” she cannot rest on mere argument that “competitive lines of the same product are designed somewhat differently, and argument of counsel that the product is unreasonably dangerous.” *James v. Swiss Valley AG Serv.*, 449 N.W.2d 886, 890 (Iowa Ct. App. 1989) (quoting *Wernimont v. Intern’l Harvester Corp.*, 309 N.W.2d 137, 142 (Iowa Ct. App. 1981)).

In this case, Ms. Nicholson’s M2a Magnum hip implant became loose, and that loosening led to a revision surgery and removal of the M2a Magnum system. SUMF ¶¶ 70–72, 74, 77–78, 127. But the fact that Ms. Nicholson’s M2a Magnum was revised is not enough to establish a product defect. “It is axiomatic that the mere fact that an accident occurred, alone, does not demonstrate that the product involved was defective.” *Housley v. Orteck Intern’l, Inc.*, 488 F. Supp. 2d 819, 828 (S.D. Iowa 2007). This is particularly true with medical devices because a patient’s medical history can impact the survivorship of a device. *See Benedict*, 405 F. Supp. 2d at 1034 & 1034 n.2. Identifying the cause or causes of a hip implant to fail – design or otherwise – is not within an average juror’s knowledge and experience.

Expert testimony was necessary to prove causation in a closely analogous case involving a Zimmer hip implant in *Benedict*, 405 F. Supp. 2d 1026. The *Benedict* court concluded that expert evidence was required to survive summary judgment challenging plaintiffs’ design defect and

failure to warn or instruct defect claims. *Id.* at 1033. The court noted, “Any decision which pertains to the design of the [hip] device involves engineering, metallurgical and medical principles beyond common knowledge and experience.” *Id.* The court concluded the plaintiffs had to present some expert testimony to prove that the complex medical device caused Plaintiff’s injuries. *Id.* at 1034. Plaintiffs failed to do so, and their claims were all dismissed. *Id.* at 1034–36.

As more fully demonstrated in Biomet’s *Daubert* motion to exclude, Ms. Nicholson’s only case-specific expert Steven E. Naide, M.D. does not provide an admissible opinion as to what caused Ms. Nicholson’s hip implant to fail and her need for revision. It is axiomatic that where an element of a claim requires expert testimony and the court excludes the expert who was to provide that testimony, the claim necessarily fails as a matter of law. *See, e.g., Barrett v. Rhodia, Inc.*, 606 F.3d 975, 985 (8th Cir. 2010) (“Because expert testimony is required to prove causation under Nebraska law and appellants’ expert testimony was properly excluded by the district court, they were unable to make out a prima facie case of strict liability based on product defect or failure to warn.”); *Farm Bureau Property & Cas. Ins. Co. v. CNH Indus. Am., LLC*, No. C16-3122-LTS, 2018 WL 2077727, at *20 (N.D. Iowa Feb. 5, 2018) (holding exclusion of expert testimony regarding warnings and instructions was fatal to plaintiffs’ claims in light of no other evidence to establish the necessary element of causation); *Ranes v. Adams Labs. Inc.*, 778 N.W.2d 677, 697 (Iowa 2010) (affirming grant of summary judgment for lack of factual question for the jury on the issue of causation after Plaintiff’s expert testimony was excluded). If the Court grants Biomet’s motion to exclude Plaintiffs’ expert with respect to either defect or medical causation, all of Plaintiffs’ claims fail as a matter of law.

D. All of Plaintiffs’ claims fail for lack of medical causation because they have no expert evidence linking a defect in the M2a Magnum device to Ms. Nicholson’s injuries and because Biomet’s experts disprove Plaintiffs’ claims.

Even if the Court were to deny Biomet’s *Daubert* motion to exclude Plaintiffs’ case-specific expert Dr. Naide’s opinions, Biomet is nevertheless entitled to summary judgment on all of Plaintiffs’ claims because Plaintiffs still cannot establish medical causation with their experts’ opinions. Medical causation is an essential element in all cases where a plaintiff seeks recovery for personal injuries resulting from an allegedly defective product. The plaintiff must establish a causal link between a product defect and the plaintiff’s injuries. Indeed, Plaintiffs are required to show that Ms. Nicholson’s injuries were *caused* by an established defect:

- Pursuing a **design defect** claim (Count 2), regardless of whether framed as a negligence or strict liability claim³, requires the Plaintiff must show that the design defect was a cause of plaintiff’s damage. *See Wright*, 652 N.W.2d at 168–69 (“One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property *caused by the defect*.” (quoting Restatement (Third) of Torts: Prod. Liab. § 1, at 5) (emphasis added)); Iowa Model Civil Jury Instructions 1000.2.
- To recover under the theory of **failure-to-warn products liability** (Count 4 & Count 5), a plaintiff must prove that the omission of the warning rendered the product unsafe and the omission of the warning was a cause of plaintiff’s damages. *See Wright*, 652 N.W.2d at 168–69; Iowa Model Civil Jury Instructions 1000.3. There are two causation elements involved in a failure-to-warn claim: 1) the product for which there was no or an inadequate warning *must have caused plaintiff’s injuries*; and (2) the plaintiff must show a warning would have altered her behavior. *See generally Security Nat’l Bank of Sioux City, Iowa v. Abbott Labs.*, 947 F. Supp. 2d 979, 999-1000 (N.D. Iowa 2013) (emphasis added).
- A **manufacturing defect** claim (if still viable) requires proof that the manufacturing defect contributed to causing plaintiff’s harm. *Nationwide Agribusiness Ins. Co.*, 816 F. Supp. 2d at 663.

³ Biomet notes that it is inappropriate to submit “both a negligence claim and a strict liability claim based on the same design defect” to a jury. *Wright*, 652 N.W.2d at 169. Iowa courts instead prefer labeling claims as “a design defect claim without reference to strict liability or negligence.” *Id.* If any portion of Plaintiffs claims survive summary judgment — which they should not — this Court should treat and submit the design defect claim to the jury as a single design defect claim. *Id.*; *Farm Bureau Property & Cas. Ins. Co.*, 2018 WL 2077727, at *17.

- To succeed on a **negligence claim** (Count 5), a plaintiff must prove (1) the existence of a duty; (2) failure to conform to that duty; (3) causation; and (4) damages. *Stotts v. Eveleth*, 688 N.W.2d 803, 807 (Iowa 2004).
- To establish a claim for **breach of express warranty** (Count 6), a plaintiff must prove that the breach of the express warranty was a *proximate cause* of the plaintiff's damage. *See Nationwide Agribusiness Ins. Co.*, 816 F. Sup. 2d at 679 & 679 n.14; *see also* Iowa Model Civil Jury Instruction 1100.1.

Here, Plaintiffs' products liability claims require expert opinions on whether any claimed defect in the M2a Magnum *caused* Ms. Nicholson's claimed injuries and the need for her revision surgery. Plaintiffs cannot meet their burden because they have no expert evidence linking any specific defect in the M2a Magnum device or its warnings to Ms. Nicholson's injuries. For the reasons described in detail below, Plaintiffs' case-specific expert, Steven E. Naide, M.D., their common-issue experts, and their non-retained expert (*i.e.* Ms. Nicholson's surgeon Dr. Li) do not establish medical causation.

1. Dr. Naide's case-specific opinions on medical causation are insufficient to generate a genuine issue of material fact on the element causation because he does not identify any defect specific to the M2a Magnum that caused Plaintiffs' injuries.

Dr. Naide's purported expert opinions on defect and causation are not sufficiently supported to create a genuine issue of material fact. To establish medical causation, a plaintiff must present conclusions that are supported by facts from the record and scientific analysis. *See Benedict*, 405 F. Supp. 2d at 1034. Conclusory testimony as to the existence of a defect or causation is not sufficient. *Id.*

Dr. Naide's testimony is conclusory and is not supported by facts or analysis. Dr. Naide's report merely says, "It is my opinion that the Biomet M2a implant with metal on metal was the cause of her elevated metal ions and need for revision surgery." *See* SUMF, ¶ 98. Dr. Naide did not provide any analysis regarding why he believes the design of the M2a Magnum caused elevated

metal ions or why elevated metal ions from the M2a Magnum caused Ms. Nicholson's revision surgery.

Dr. Naide's disclosed opinions are premised on guesswork, not facts. Dr. Naide admitted that he had never implanted a Biomet M2a hip system, and he does not remember ever seeing a Biomet M2a implant. *See* SUMF, at ¶ 99. Dr. Naide was unable to provide an opinion specifically to the Biomet M2a Magnum's design, instead saying his criticisms were "more general." *See* SUMF ¶ 102. Dr. Naide expressed no opinion as to whether the M2a Magnum complied with federal regulations, and he had no opinions as to the sufficiency of the warnings given to Ms. Nicholson or her surgeon about the M2a Magnum. *See* SUMF ¶ 95.

Dr. Naide's only background knowledge regarding the M2a Magnum's design comes from an MDL common-issue expert, Dr. George Kantor.⁴ *See* SUMF ¶ 103. But Dr. Kantor has been precluded from testifying at trial about "the risks associated with and the design defects of Biomet devices because he had not considered sufficient data in developing his opinion." *See* Doc. 215, Transfer Order, at 8. Thus, Dr. Naide's understanding of the Biomet M2a Magnum is not sufficient to allow him to develop a causal link between the M2a Magnum's design and Ms. Nicholson's alleged injuries.

Even if this dubious understanding of the M2a Magnum's design was sufficient to generate an opinion on defect, Dr. Naide's opinions on causation also have no grounding in Ms. Nicholson's medical history. Dr. Naide testified that some hip implants cause metallosis, which he defines as having elevated serum cobalt and chromium. *See* SUMF ¶ 104. But metallosis is not a unique risk for metal-on-metal hips; it can also occur with other articulations, such as ceramic on polyethylene. *See* SUMF ¶¶ 105–06. Elevated serum cobalt and chromium levels – at least at the

⁴ Plaintiffs did not disclose that Dr. Naide had reviewed Dr. Kantor's report in forming his expert opinions.

levels observed in Ms. Nicholson – standing alone are not enough to justify a revision surgery. *See* SUMF ¶ 107.

In Dr. Naide’s experience, “[o]ftentimes when failure occurs because of metallosis there is a significant amount of soft tissue destruction making the revisions difficult.” *See* SUMF ¶ 135. But Dr. Naide’s described failure mechanism did not happen in Ms. Nicholson’s case. Ms. Nicholson’s revision surgery was not difficult. *See* SUMF ¶ 84. Nor did her revision surgeon encounter any tissue destruction during the revision surgery. *See* SUMF ¶ 82. In light of these facts, Dr. Naide could not point to any evidence that Ms. Nicholson’s elevated metal ion levels caused any tissue damage.

In sum, Dr. Naide fails to establish that any alleged defect in the M2a Magnum hip led to Ms. Nicholson’s revision surgery. The lack of case-specific evidence linking an alleged design defect to Ms. Nicholson’s injuries are fatal to Plaintiffs claims, so they should be dismissed as a matter of law.

2. Plaintiffs’ retained common-issue experts do not establish specific medical causation.

Plaintiffs’ common-issue experts – Mari Truman, M.S. P.E., George S. Kantor, M.D., and Francis H. Gannon, M.D. – do not help Plaintiffs meet their burden of establishing medical causation either. These common issue experts do not establish causation with respect to Ms. Nicholson. *See* SUMF ¶ 109. These experts address *only* common issues and none of them offer any opinion that any specific defect in Ms. Nicholson’s M2a Magnum was the medical cause of her injuries and need for revision surgery. *See* SUMF ¶ 109.

3. Plaintiffs’ non-retained treating expert Dr. Li cannot and does not establish medical causation.

Plaintiffs have designated Ms. Nicholson’s orthopedic surgeon, Dr. Emile Li as a non-retained expert. *See* SUMF ¶ 112. Dr. Li does not establish medical causation linking an alleged

defect in Ms. Nicholson's M2a Magnum device to Ms. Nicholson's alleged injuries. Indeed, Dr. Li expressly stated that he could not determine the etiology or the cause of the loosening of Ms. Nicholson's prosthesis. *See* SUMF ¶ 113. Dr. Li further testified that he had not undertaken any scientific study or analysis to develop an opinion about the design of the M2a hip system. *See* SUMF ¶ 83.

Even if he had testified as to causation (which he does not), any testimony from Dr. Li is expressly limited to his diagnosis, prognosis, and treatment of Ms. Nicholson. To the extent a treating expert goes beyond their diagnosis, prognosis, and treatment to opine on causation, their expert opinions must be disclosed pursuant to Rule 26(a)(2). *See Vanderberg v. Petco Animal Supplies Stores, Inc.*, No. C16-4019-LTS, 2017 WL 2695302, at * 6 (N.D. Iowa June 22, 2017), *reconsideration denied*, No. C16-4019-LTS, 2017 WL 3016164 (N.D. Iowa July 14, 2017), and *aff'd*, 906 F.3d 698 (8th Cir. 2018) ("The law in this circuit is clear that a treating physician's opinions as to causation are, in fact, expert opinions that must be disclosed pursuant to Rule 26(a)(2)."). Here, Plaintiffs did not disclose Dr. Li as an expert who would testify as to causation. *See* SUMF ¶ 112. Therefore, his testimony or opinions cannot generate a genuine issue of material fact with respect to causation as a matter of law.

4. The only admissible expert evidence – Biomet's evidence – establishes that Ms. Nicholson's M2a Magnum did not cause Ms. Nicholson's alleged injuries.

Dr. Naide's inadmissible opinion on causation is directly contradicted by the testimony of Biomet's case-specific engineering expert, Dr. Steven Kurtz, and medical expert, Dr. Charles Clark. Dr. Kurtz's and Dr. Clark's testimony affirmatively establish that Ms. Nicholson's need for a revision surgery was related to patient and clinical factors, not the M2a Magnum device itself. Because the undisputed evidence disproves Plaintiffs' claims, summary judgment should be entered in Biomet's favor.

Biomet has presented admissible expert testimony to establish that Ms. Nicholson's device exhibited metal wear consistent with a well-functioning metal-on-metal hip implant. Biomet designated and produced the expert report of Dr. Kurtz, who analyzed Ms. Nicholson's explanted M2a Magnum components. *See* SUMF ¶ 119. Dr. Kurtz explained that metal-on-metal hip implants are expected to wear at a rate of between 1 to 5 mm³/year. *See* SUMF ¶ 120. Ms. Nicholson's left hip implant exhibited a wear rate of less than 3 mm³/year. *See* SUMF ¶ 121. Dr. Kurtz determined that her articulating surfaces had a rate of material loss that was within the expected range published in the literature, and that was consistent with what would be expected in a biomechanically well-functioning metal-on-metal articulation. *See* SUMF ¶ 122. Dr. Kurtz further explained that "[t]he need to revise [a] grossly loose acetabular cup[] is independent of the type of material used for the bearing surface." *See* SUMF, at ¶ 136. Dr. Kurtz further opined that based on the patient and clinical factors in this case, there was no evidence that using an alternative bearing would have prevented the need for Ms. Nicholson's revision surgery. *See* SUMF ¶ 125.

Biomet further produced the expert testimony of Dr. Clark, a medical doctor who performs hip replacement surgeries and teaches and presents on the topic of hip implants. Unlike Dr. Naide, Dr. Clark is, without question, qualified to render an opinion on medical causation. Dr. Clark opines that based on his analysis of Ms. Nicholson's medical records, x-rays, and deposition that Ms. Nicholson's need for revision surgery was unrelated to Ms. Nicholson's devices themselves. SUMF ¶ 126. Dr. Clark opines that Ms. Nicholson needed revision surgery because her acetabular cup loosened— a known (and warned of) complication for any hip implant. *See* SUMF ¶¶ 127–28. Dr. Clark opines that Ms. Nicholson's history of smoking and her small central medial wall crack in her acetabulum also contributed to the loosening of the cup. *See* SUMF ¶¶ 129–30. Dr. Clark further explains that the looseness caused the cup to migrate to a vertical orientation of the cup,

which then became painful. *See* SUMF ¶ 131. Finally, Dr. Clark notes that Ms. Nicholson's metal ion levels were not considered concerning. *See* SUMF ¶ 132. Dr. Clark opines that Ms. Nicholson's course would have occurred with any porous hip implant due to the lack of bony-ingrowth. *See* SUMF ¶ 133.

Because Dr. Naide's opinions are inadmissible and he does not point to any alleged product defect as the medical cause of Ms. Nicholson's revision surgery, Dr. Clark's opinion on medical causation is unrefuted. Ms. Nicholson's acetabular cup loosened due to patient specific factors, particularly smoking, which led to migration of the cup and pain. *See* SUMF ¶ 132. Put simply, Ms. Nicholson's revision surgery was not caused by any alleged defect in the M2a Magnum. Accordingly, there is no genuine issue of material fact on medical causation, and Biomet is entitled to summary judgment on all of Plaintiffs' claims for this reason alone.

In sum, Plaintiffs' case-specific expert Dr. Naide's opinions do not prove medical causation or defect, none of Plaintiffs' common-issue experts even purports to offer specific causation opinions with respect to Ms. Nicholson, the testimony of Ms. Nicholson's surgeon Dr. Li is limited to his medical treatment of Ms. Nicholson and he does not offer a causation opinion, and Biomet's expert evidence disproves Plaintiffs' claims. Without expert testimony that a defect *caused* Ms. Nicholson's injuries, Plaintiffs cannot prove the essential element of medical causation and Biomet is entitled to judgment as a matter of law on *all* of Plaintiffs' product liability claims *for this reason alone*.

E. Plaintiffs' warning claims fail as a matter of law because the Magnum device's IFU is adequate and for lack of causation.

Plaintiffs allege that Biomet is liable for failure to warn of the risks of Ms. Nicholson's Magnum device. Plaintiffs raise their failure to warn claim in two counts – Count IV (strict liability) and Count V (negligence). At the outset, failure to warn claims should be brought as

negligence claims, not strict liability, so Plaintiffs' strict liability failure to warn claim should be dismissed. *See Lamb v. Manitowoc Co., Inc.*, 570 N.W.2d 65, 68 (Iowa 1997). Regardless, Plaintiffs' warning claims fail as a matter of law.

Iowa has adopted Section 2(c) of the Restatement for failure to warn cases, under which “[a] product . . . is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller . . . and the omission of the instructions or warnings renders the product not reasonably safe.” *Neilson v. Whirlpool Corp.*, No. 3:10-cv-00140-JAJ-RAW, 2012 WL 13018693, at *11 (S.D. Iowa Jan. 3, 2012). This claim “specifically requires the plaintiff to show that the foreseeable risk of harm could have been reduced or avoided with reasonable instructions or warnings.” *Id.*

Plaintiffs' warning claims fail for at least three reasons. First, Biomet discharged its duty to warn by informing Plaintiff's surgeon, Dr. Emile Li, of the risks associated with the device. This concept is known as the learned intermediary doctrine. Second, Biomet's warnings were adequate as a matter of law because they identified all of the alleged modes of failure of Ms. Nicholson's M2a Magnum: (1) loosening or migration of the implants; (2) corrosion; (3) wear; (4) elevated metal ion levels; and (5) material sensitivity reactions that could be associated with osteolysis or osteolysis may be a result of loosening of the implant. Third, Plaintiffs' cannot establish that different warnings would have had any impact on Ms. Nicholson's treatment.

1. Biomet discharged its duty to warn by providing an adequate warning to Ms. Nicholson's surgeon, Dr. Li.

Biomet is entitled to summary judgment on Plaintiff's failure to warn claims pursuant to the learned intermediary doctrine. The “learned intermediary rule” allows manufacturers of prescription drugs and medical devices discharge their duty of care to patients by warning the

health-care providers who prescribe and use the drugs or devices to patients. *See Gilliland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 960, 969 (S.D. Iowa 2014) (citing Restatement (Third) of Torts: Prods. Liab. § 6 cmt. D); *Nationwide Agribusiness Ins.*, 816 F. Supp. 2d at 654 (stating the intermediary defense in Iowa would not be limited to “the context of prescription drugs and medical devices”). Under the learned intermediary rule (or doctrine) the health-care provider acts as an intermediary by warning the patient of the risks involved with the treatment. *See Gilliland*, 34 F. Supp. 3d at 969. A warning to a health-care provider is therefore deemed a warning to the patient. *Madsen v. Am. Home Prod. Corp.*, 477 F. Supp. 2d 1025, 1034 (E.D. Mo. 2007). Under the learned intermediary doctrine, Biomet had a duty to warn only Plaintiff’s physician and had no duty to warn Plaintiff directly.

Iowa state courts have never squarely addressed the learned intermediary doctrine. Yet, the Iowa Supreme Court has identified the learned intermediary doctrine as one example of a “‘no duty’ rule in the warning area based on principles analogous to lack of control,” *see McCormick v. Nikkel & Assocs., Inc.*, 819 N.W.2d 368, 375 (Iowa 2012) (citing the Restatement (Third) of Torts: Prod. Liab. § 6(d))⁵, and federal courts have regularly and consistently predicted that Iowa will adopt the doctrine. *See Madsen*, 477 F. Supp. 2d at 1034 (applying Iowa law and holding that “Iowa’s adoption of the Restatement (Third) of Torts analytical framework for product defect cases and the overwhelming precedent adopting the learned intermediary doctrine convinces the Court that the Iowa Supreme Court would recognize that the doctrine governs Plaintiff’s failure-to-warn claims at issue.”); *see also Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (indicating

⁵ *See also Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 360 & 360 n.4 (Iowa 2014) (observing a learned intermediary argument may have been presented at the summary judgment stage, but it was not at issue on appeal); *Thompson v. Kaczinski*, 774 N.W.2d 829 (Iowa 2009) (citing to The Restatement (Third) of Torts: Prod. Liab. § 6 cmt. f, which discusses the learned intermediary doctrine, and explaining that the general duty to exercise reasonable care can be displaced or modified in exceptional cases).

that the doctrine is part of Iowa’s common law, but refusing to apply it in a mass immunization context “where there is no learned intermediary”); *Gilliland*, 34 F. Supp. 3d at 969 (“To survive summary judgment, *Gilliland* must demonstrate a genuine fact issue as to whether Novartis adequately warned her oncologist—*not her*—of the connection between bisphosphonates and the risk of ONJ.”) (emphasis in original); cf. *Daughetee v. Chr. Hansen, Inc.*, 960 F. Supp. 2d 849, 870 (N.D. Iowa 2013) (explaining the “intermediary defense” is a viable defense to a warning defect claim under Iowa law based on the duty of an intermediary to warn the end user).

Iowa’s adoption of the learned intermediary doctrine would fall in line with the majority of jurisdictions that employ some iteration of the learned intermediary doctrine. “In 2012, the Texas Supreme Court counted thirty-five states, including the District of Columbia, in which the high court has ‘adopted some form of the learned intermediary doctrine within the prescription drug product-liability context’ or that has at least ‘cited favorably to its application within this context.’” *Tyree v. Boston Scientific Corp.*, 56 F. Supp. 3d 826, 834 n. 3 (S.D. W. Va. 2014) (citing *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 n. 17 (Tex. 2012)). Further, “state intermediate courts or federal courts of thirteen other states have applied the learned intermediary doctrine or predicted that the highest state court would apply it.” *Id.* (citations omitted). Likewise, “[i]n *In re Norplant [Contraceptive Products Liability Litigation]*, 215 F. Supp. 2d 795 (E.D. Texas 2002)], the court determined that 48 states, the District of Columbia and Puerto Rico apply the learned intermediary doctrine to define a pharmaceutical company’s duty to warn of risks associated with the use of a prescription drug.” *Madsen*, 477 F. Supp. 2d at 1033–34. The *Norplant* court cited to *Petty* in determining that the learned intermediary doctrine is part of Iowa’s common law. *Id.* at 1034. In *Petty*, the court acknowledged the learned intermediary doctrine but

held that in the mass immunization context—“where there is no learned intermediary”—the duty to warn extends to the ultimate consumer. *Petty*, 740 F.2d at 1440.

Arguments in favor of applying the learned intermediary doctrine are compelling in a medical device case. Under the learned intermediary doctrine, the duty to warn runs to the treating physician—the learned intermediary—because “physicians are in a better position to convey information to patients than manufacturers.” *See Madsen*, 477 F. Supp. 2d at 1033. As one district court noted, “it makes even more sense to apply the doctrine in the context of medical devices,” especially as compared to drug and vaccine cases. *See Tyree*, 56 F. Supp. 3d at 833. While a plaintiff may request a vaccine without the intervention of a physician or self-administer a prescription drug, a plaintiff cannot perform her own orthopedic surgery. For a patient to use a prosthetic device such as the M2a Magnum, she must find an orthopedic surgeon to implant it using the surgeon’s superior knowledge to perform the surgery. The surgeon therefore “acts as a ‘learned intermediary’ between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated with the [device].” *See Madsen*, 477 F. Supp. 2d at 1033. Indeed, under Iowa law, “a doctor recommending a particular procedure generally has, among other obligations, the duty to disclose to the patient *all material risks involved in the procedure*.” *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 358 (Iowa 1987) (emphasis added). Thus, any warnings provided directly to a patient by the device manufacturer are redundant.

Additionally, adoption of the learned intermediary doctrine would be consistent with Iowa’s sophisticated user defense. *See West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202, 210 (Iowa 1972) (applying Restatement (Second) of Torts § 388(b) and comment n in a failure to warn case to determine whether the manufacturer of a wire rope sling had a duty to warn

ironworkers, the end users of the product, in light of their professional expertise).⁶ The sophisticated user defense imposes “no duty to warn if the user knows or should have known of the potential danger, especially when the user is professional who should be aware of the characteristics of the product.” *See Bergfeld v. Unimin Corp.*, 319 F.3d 350, 353 (8th Cir. 2003) (applying Iowa law). The sophisticated user defense is effectively a corollary of the learned intermediary doctrine, which holds that a medical device warning should be directed to the person who would act on the warning—the doctor who will select and implant the device. Courts applying Iowa law have blurred the line between the two doctrines. *See e.g. Daughetee*, 960 F. Supp. 2d at 870 (“Restatement (Third) § 2(c) and comment i recognize a defense to a warning defect claim based on the duty of an intermediary—and not even necessarily a ‘learned’ or ‘sophisticated’ intermediary—to warn the end user.”).

In accordance with *Gilliand*, *Daughetee*, and the sophisticated user defense Iowa has already adopted, and consistent with the vast majority of jurisdictions, the Court should apply the learned intermediary doctrine here. The Biomet M2a Magnum hip replacement system is a prescription medical device only available through a physician, and Biomet’s duty to warn was thus owed to Plaintiff’s treating physician, not to Plaintiff.

Put simply, under the learned intermediary doctrine a medical device manufacturer discharges its duty to warn by warning a patient’s prescribing physicians and is otherwise relieved from liability for lack of causation if the prescribing physician had independent knowledge of the device’s risks. An analysis of Biomet’s IFU and application of the learned intermediary doctrine

⁶ Section 388(b) provides that a supplier of a product to a third party has a duty to warn the ultimate user if the supplier has no reason to believe the end user will realize its defective or dangerous condition. Pursuant to comment n to § 388, a supplier may discharge its duty to warn an end user by providing a warning to a third party, under certain circumstances.

and the law of proximate causation to the undisputed facts demonstrate that Biomet is entitled to summary judgment on Plaintiffs' warning claims.

2. Biomet's IFU is adequate and warned Dr. Li of the risks of adverse tissue reactions, "loosening," "material sensitivity reactions," and "metal hypersensitivity," among other risks.

At the crux of Plaintiffs' case is their claim that Ms. Nicholson's hip implant loosened due to loss of bone fixation and/or loosening of her cup due to elevated metal ion levels. Biomet's Magnum IFU expressly addresses these risks:

- The IFU warns of "Material sensitivity reactions" as follows:

Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. . . . Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. *It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.* A low incidence of metal hypersensitivity has been reported with failed metal on metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure."

SUMF ¶ 37.

- The IFU further warned of elevated metal ion levels:

Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown."

SUMF ¶ 39.

- The IFU also addressed the risk of loosening:

Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, or excess activity.

See SUMF ¶ 38.

- The IFU also warned of corrosion as follows:

Fretting and crevice corrosion may occur at interfaces between components.

See SUMF ¶ 110.

- The IFU expressly warned that wear could occur at the articulating surfaces:

Wear and/or deformation of articulating surfaces.

See SUMF ¶ 111.

Plaintiffs' warning claims fail at the threshold because Biomet's IFU for the Magnum is adequate as a matter of law. It cannot be disputed that the IFU warns of the complications that Plaintiffs (and Dr. Naide) claim Ms. Nicholson experienced with her hip implant – loosening, “material sensitivity reactions,” corrosion, wear, and elevated metal ion levels. See SUMF ¶¶ 37–39, 110–11. Because the Magnum IFU warned of the complications that Plaintiffs (and Dr. Naide) claim Ms. Nicholson experienced with her hip implant, the warnings are adequate as a matter of law, and Biomet is entitled to summary judgment. See *Parish v. Jumpking, Inc.*, 719 N.W.2d 540, 545–46 (Iowa 2006) (granting defendants' motion for summary judgment where it was undisputed that the warnings that came with the product “warned against the specific conduct in which the plaintiff was engaged at the time of his injury”).

3. Plaintiffs cannot establish that any alleged failure to warn caused Ms. Nicholson's injuries.

Notwithstanding the adequacy of Biomet's IFU, Plaintiffs' warning claims fail for lack of causation. As discussed above (*see* Section D.), there are *two* causation elements in a failure to warn claim: (1) the product for which there was no or an inadequate warning must have caused plaintiff's injuries; and (2) the plaintiff must show a warning would have altered her behavior. See generally *Security Nat'l Bank of Sioux City, Iowa*, 947 F. Supp. 2d at 999-1000. The court may properly enter summary judgment in favor of the defendant if either element of causation is lacking. *Id.* The first element of causation is lacking here because Plaintiffs cannot show that a defect in the Magnum caused Plaintiffs' injuries (*see* Section D.). Plaintiffs' warning claims fail

for the *additional independent* reason that Plaintiffs cannot satisfy the second element of causation – that a warning would have altered the behavior of Ms. Nicholson’s treating physician and the learned intermediary Dr. Li.

Plaintiffs cannot establish the second element of causation because Plaintiffs cannot establish that Dr. Li would have selected a different device if he had received different warnings. Dr. Li testified that he selected the Biomet M2a Magnum based on his judgment and clinical experience with the device. *See* SUMF ¶ 115. Dr. Li placed far greater weight on his clinical experience with the implant than on any information contained within the IFU. *See* SUMF ¶ 116. Indeed, Dr. Li does not recall whether he read Ms. Nicholson’s M2a Magnum’s IFU prior to her implantation surgery. *See* SUMF ¶ 134. Further, Dr. Li did not rely on any information provided by Biomet sales representatives. *See* SUMF ¶ 118. Dr. Li also testified that he was aware of all the risks listed in the IFU when he decided to select the M2a Magnum for Ms. Nicholson’s hip replacement surgery in July 2007. *See* SUMF ¶ 40. As of the date of his deposition, Dr. Li still believed that he made the right choice when he selected the Biomet M2a Magnum for Ms. Nicholson’s surgery in 2007. *See* SUMF ¶ 42.

Further, Ms. Nicholson’s own testimony proves that even if Biomet somehow bypassed the learned intermediary and provided duplicative warnings directly to Ms. Nicholson (which Biomet was not obligated to do), her treatment would have been the same. Ms. Nicholson testified that she trusted Dr. Li to select the correct implant for her. *See* SUMF ¶ 26. She did not personally select the Biomet M2a Magnum based on any marketing materials or brochures from Biomet. *See* SUMF ¶ 32. Although she knew Dr. Li would be using a Biomet M2a Magnum device, she did not research the device at all before the surgery. *See* SUMF ¶ 27. Moreover, she did not ask Dr. Li

any questions about the M2a Magnum. *See* SUMF ¶ 29. Therefore, there is no evidence that she personally would have requested a different device if Biomet had provided different warnings.

F. Biomet did not make any express warranties to Plaintiffs.

Plaintiffs' breach of express warranty claim (Count VI) should be dismissed because Biomet never made any express warranties to Plaintiffs. Warranty claims are based upon contract law. *Dailey v. Holiday Distributing Corp.*, 151 N.W.2d 477, 483 (Iowa 1967).

An express warranty may be created by any of the following means:

- a. Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
- b. Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- c. Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Iowa Code Ann. § 554.2313. An affirmation of the value of the goods or a statement of the seller's opinion, however, is insufficient to create a warranty. *Id.*

Here, Plaintiffs have not identified any statements that formed the basis of the bargain for selecting the M2a Magnum. In fact, Ms. Nicholson testified that she did not personally select the M2a Magnum prosthesis for use in her total hip arthroplasty. SUMF ¶¶ 24, 31-32. Further, Ms. Nicholson explained that she did not base her decision to move forward with a Biomet M2a implant based on any information received from Biomet:

Q. You didn't select the Biomet M2a implant based on any marketing materials or brochures from Biomet; is that correct?

[objection]

A. No, I didn't.

Q. So you said no, you didn't select it based on any marketing materials?

[objection]

A. No. I think Dr. Li pretty – No, I didn't. I think Dr. Li pretty much said, "This is what we're going to get," and just showed me what it looked like.

....

Q. [D]id you review any other marketing materials about—

A. No.

Q. – Biomet M2a?

A. No.

Q. Did you have any contact with any Biomet employees or sales representatives?

A. No.

Q. You didn't select the Biomet M2a implant based on any statements from Biomet employees?

A. No.

Q. And you didn't select it based on any statements from Biomet sales representatives either?

A. No.

SUMF ¶ 32.

This exchange shows that Ms. Nicholson did not select the device based on any representations made by Biomet, so Biomet's information could not have formed the basis of the bargain for the use of the M2a Magnum in Ms. Nicholson's surgery. Therefore, the breach of express warranty claim (Count VI), should be dismissed.

G. Plaintiffs' fraud, misrepresentation, and breach of implied warranty of fitness for a particular purpose claims fail for lack of reliance.

Plaintiffs' fraud claims cannot succeed because the record is absent of any indicia that Ms. Nicholson or her surgeon, Dr. Li, relied on any information or marketing from Biomet to select the M2a Magnum for Ms. Nicholson's hip replacement surgery. Iowa law requires proof of reliance for several of Plaintiffs' misrepresentation claims:

- To establish a claim for **breach of the implied warranty of fitness for a particular purpose** (Count 8) requires proof that the buyer relied on the manufacturer's skill or judgment to furnish suitable goods. *See SmithCo Mfg., Inc. v. Haldex Brake Prod. Corp.*, 708 F. Supp. 2d 816, 820 (N.D. Iowa 2010).
- To establish a claim for **negligent misrepresentation** (Count 9), a plaintiff must show that the defendants' actions caused the plaintiff to act in justifiable reliance upon the false information provided by the defendants. *Bagelmann v. First Nat'l Bank*, 823 N.W.2d 18, 30 (Iowa 2012).
- To prove a claim of **fraudulent misrepresentation** (Count 10), the plaintiff must prove both reliance and resulting injury and damage. *See Stone v. Ford*, 919 N.W.2d 635 (Iowa Ct. App. 2018).

- A claim of **fraudulent concealment** (Count 11) similarly requires proof that the plaintiff did in fact rely upon defendants' representations to his prejudice. *Estate of Anderson ex rel. Herren v. Iowa Dermatology Clinic, PLC*, 819 N.W.2d 408, 414 (Iowa 2012).

“The Iowa Supreme Court has made clear that, among other elements, ‘[t]o bring a fraud claim, the plaintiff must have justifiably relied on the false representation.’” *Security Nat’l Bank of Sioux City, Iowa*, 947 F. Supp. 2d at 995 (quoting *Dier v. Peters*, 815 N.W.2d 1, 9 (Iowa 2012)). This means that Plaintiffs must produce some evidence that Ms. Nicholson’s decision to move forward with the implantation of the Biomet M2a Magnum was influenced by false statements or representation made by Biomet. *See id.* at 996.

As discussed above in Section E., Ms. Nicholson and her surgeon, Dr. Li, did not rely on any statements of Biomet to select the M2a Magnum for use in Ms. Nicholson’s left total hip arthroplasty. Therefore, her fraud, misrepresentation, and breach of implied warranty claims (Counts 8, 9, 10, 11) should be dismissed as a matter of law.

H. Iowa law does not recognize a strict liability claim for defect due to nonconformance with representations.

Plaintiffs’ third cause of action, strict products liability-defect due to nonconformance with representations, should be dismissed because Iowa does not recognize such a claim. The Iowa Supreme Court clarified the types of claims available in products defect cases in *Wright*, 652 N.W.2d 159. Conspicuously absent is any discussion of a strict liability for nonconformance with representation cause of action. Undersigned counsel has found no authority to support application of this claim in Iowa courts.

Biomet further notes that the claim for defect due to nonconformance with representations seems to overlap with Plaintiffs’ fraud-based claims. *Compare* Doc. 1, Compl., at ¶¶ 62–69, *with* Doc. 1, Compl., at ¶¶ 120–32. Plaintiffs should not be allowed to repackage their fraud, warranty, or product defect-based claims under the guise of a new strict liability cause of action without a

legal basis to do so. *See Nationwide Agribusiness Ins. Co.*, 816 F. Supp. 2d at 664–65 (“While it is not necessarily impermissible to allege an alternative theory of recovery for the same allegedly wrongful conduct, there must be a legal and factual basis for the alternative theory.”). Biomet submits that it is highly unlikely that Iowa state courts would agree to expand the scope of strict liability in light of the Iowa Supreme Court’s movement away from strict liability towards a negligence standard in *Wright*. Therefore, Plaintiffs’ strict products liability-defect due to nonconformance with representations (Count 3) should be dismissed.

I. Plaintiffs’ claim for punitive damages should be dismissed because Iowa does not recognize a separate claim for punitive damages, and Plaintiffs cannot otherwise meet the high standard for an award of punitive damages.

Plaintiffs’ cause of action titled “Punitive Damages” and their general requests for an award of punitive damages should be dismissed as a matter of law. Plaintiffs are not entitled to punitive damages for multiple reasons.

First, Plaintiffs’ cause of action titled “Punitive Damages” fails at the threshold because Iowa does not recognize a separate cause of action for punitive damages. *Campbell v. Van Roekel*, 347 N.W.2d 406, 410 (Iowa 1984). Rather, punitive damages are “merely incidental to the main cause of action.” *Id.* Therefore, Plaintiffs’ punitive damage claim (Count 12) should be dismissed on its face.

Second, to the extent that Plaintiffs’ underlying product liability claims fail, those claims cannot support a claim for punitive damages. It is well settled that there can be no recovery for punitive damages unless actual and substantial compensatory damages are first shown. *See McCarthy v. J.P. Cullen & Son Corp.*, 199 N.W.2d 362, 368 (Iowa 1972); *see also Campbell*, 347 N.W.2d at 410 (“Punitive damages are merely incidental to the main cause of action.”). Because Plaintiffs’ substantive product liability claims fail as a matter of law, Plaintiffs’ request for punitive damages likewise fails as a matter of law.

Third, even if the Court were to find that one or more of Plaintiffs' product liability claims survives summary judgment, Biomet is still entitled to summary judgment with respect to punitive damages because Plaintiffs cannot as a matter of law meet the high standard for punitive damages. Although Iowa law governs Plaintiffs' claims for compensatory damages, a choice of law analysis on the issue of punitive damages is not as simple.

In tort cases, Iowa applies the Restatement (Second) Conflict of Laws' "most significant relationship" test. *See Veasley v. CRST Int'l, Inc.*, 553 N.W.2d 896, 897 (Iowa 1996); *see also Jones ex rel. Jones v. Winnebago Indus., Inc.*, 460 F. Supp. 2d 953, 964 (N.D. Iowa 2006) (noting that Iowa federal court sitting in diversity applies Iowa choice of law rules and conducting most significant relationship analysis). The significant relationship test requires a multi-factorial analysis of the Restatement (Second) of Conflict of Laws § 145 factors considering the § 6 principles.⁷ Biomet contends that the law of Indiana, where all the Biomet conduct of which

⁷ Section 145 of the Restatement provides:

- (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.
 - (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:
 - (a) the place where the injury occurred,
 - (b) the place where the conduct causing the injury occurred,
 - (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and
 - (d) the place where the relationship, if any, between the parties is centered.
- These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second) of Conflict of Laws § 145. Section 6 of the Restatement provides:

- (1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.
- (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include
 - (a) the needs of the interstate and international systems,
 - (b) the relevant policies of the forum,
 - (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
 - (d) the protection of justified expectations,
 - (e) the basic policies underlying the particular field of law,

Plaintiffs complain occurred, should apply to Plaintiffs' punitive damages claim. *See Jones*, 460 F. Supp. 2d at 970 (“[I]n a products liability case, the place where the design, manufacture, and marketing conduct relating to the allegedly defective product occurred is of relatively greater weight than ‘the place of injury,’ at least in the absence of evidence that other conduct substantially contributing to the injury also occurred in the place of injury.”).

For purposes of summary judgment, however, the Court need not decide the choice-of-law question to grant Biomet summary judgment on Plaintiffs' punitive damages claim. Plaintiffs' evidence could not sustain an award of punitive damages under either state's standard.⁸

Iowa permits an award of punitive damages only if the claimant proves by “a preponderance of clear, convincing, and satisfactory evidence” that “conduct of the defendant from which the claim arose constituted willful and wanton disregard for the rights and safety of another.” *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 618 (Iowa 2000); Iowa Code Ann. § 668A.1(1)(a); *Lovick v. Wil-Rich*, 588 N.W.2d 688, 699 (Iowa 1999); Iowa Code Ann. § 668A.1. Under Indiana law, punitive damages may be awarded only when the jury could find by clear and convincing evidence that the defendant acted with malice, fraud, willful and wanton misconduct, oppressiveness “which was not the result of a mistake of fact or law, mere negligence, or other human failing.” *Wohlwend v. Edwards*, 796 N.E.2d 781, 784 (Ind. Ct. App. 2003); Ind. Code § 34-51-3-1.

Here, even assuming Plaintiffs could produce sufficient evidence to create a genuine issue

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- (f) certainty, predictability and uniformity of result, and
 - (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6.

⁸ While the substantive standards for liability are essentially the same, Indiana places a cap on punitive damages, and Iowa does not. There is therefore a meaningful conflict in the laws that requires resolution if the punitive damages request proceeds to trial. Biomet therefore reserves the right to submit further briefing on the choice of law issues raised by Plaintiffs' request for punitive damages as well as to request bifurcation of trial with respect to liability for compensatory damages and for an award of punitive damages.

of material fact on one or more of their product liability claims, they cannot produce evidence that could clearly and convincingly permit a jury to conclude that Biomet engaged in the culpable conduct required by either of these standards: “willful and wanton disregard” or “willful and wanton misconduct.” Plaintiffs cannot establish gross negligence, fraud, malice, wanton and willful misconduct, or wanton and willful disregard. The Court should grant Biomet summary judgment on Plaintiffs’ request for punitive damages.

J. Mr. Nicholson’s derivative loss of consortium claim fails with his spouse’s claims.

A spouse’s loss of consortium claim is wholly derivative of the injured spouse’s claims. *Benedict*, 405 F. Supp. 2d at 1036. Where the injured spouse’s claims fail, the loss of consortium claim must also fail. *See id.* (citing *Neely v. Am. Family Mut. Ins. Co.*, 930 F. Supp. 360, 376 (N.D. Iowa 1996), *aff’d*, 123 F.3d 1127 (8th Cir.1997)).

Plaintiff William Nicholson’s loss of consortium claim is derivative of his wife’s claims. If Ms. Nicholson has no valid claims, Mr. Nicholson’s loss of consortium claim necessarily fails as a matter of law. *See id.* Because Biomet is entitled to summary judgment on Lori Nicholson’s claims, Biomet also is entitled to summary judgment on William Nicholson’s loss of consortium claim (Count 13).

IV. CONCLUSION

Biomet is entitled to summary judgment on all of Plaintiffs’ claims. Plaintiffs’ claims fail due to the exclusion of Plaintiffs’ case-specific expert Dr. Naide’s opinions regarding product defect and medical causation. Even if the Court denies Biomet’s motion to exclude Dr. Naide’s opinions, Plaintiffs’ experts still fail to offer any opinions to support a claim that the M2a Magnum had any defect that *caused* Plaintiffs’ alleged injuries and *all* of Plaintiff’s claims fail for this reason alone. Plaintiffs’ failure to present expert evidence on the fundamental element of specific medial causation leaves Defendants’ experts’ testimony that the M2a Magnum did not cause Plaintiffs’

injuries unrebutted. The only admissible expert evidence – Defendants’ evidence – disproves Plaintiffs’ case and establishes that the M2a Magnum did not cause Plaintiff Lori Nicholson’s need for revision surgery. Ms. Nicholson’s need for revision surgery was caused by aseptic loosening of her acetabular component as a consequence of Ms. Nicholson’s history of smoking and the subsequent realization that there had been a small central medial wall crack of her acetabulum after the 2007 implantation.

Further, Plaintiffs’ claims fail additional reasons. Plaintiffs have abandoned their manufacturing defect claims and have identified no manufacturing defect or deficiency in the manufacturing process to avoid summary judgment in Biomet’s favor.

Biomet is entitled to summary judgment on Plaintiffs’ warning claims because the M2a Magnum device’s IFU identifies all of Ms. Nicholson’s symptoms as potential adverse effects and Plaintiffs’ cannot show that any allegedly inadequate or omitted warnings caused Ms. Nicholson’s implanting surgeon, Dr. Emile Li, to implant the M2a Magnum.

Plaintiffs’ warranty claims fail because Biomet does not provide warranties for its products, and Plaintiffs have presented no evidence to establish any warranty existed between Biomet and Plaintiffs.

Plaintiffs’ fraud-based claims and breach of implied warranty of fitness for a particular purpose fail because there is no evidence to support that Ms. Nicholson or her surgeon relied on Biomet’s package insert or advertising to select the M2a Magnum for use in her left total hip replacement. Iowa also does not recognize an independent claim for strict liability product defect—nonconformance with representations so Plaintiff’s representation-based claim fails on its face, and Plaintiffs should not be allowed to repackage their fraud, warranty, or product defect-based claims under the guise of a new strict liability cause of action without a legal basis to do so.

Biomet is entitled to summary judgment on Plaintiffs' request for punitive damages because, contrary to Plaintiffs' pleadings, punitive damages are not an independent cause of action under Iowa law, and Plaintiffs cannot otherwise meet the high standard for an award of punitive damages.

Finally, because Ms. Nicholson's claims fail, so too must Mr. Nicholson's derivative loss of consortium claim.

For all the above reasons, Biomet respectfully urges the Court to enter summary judgment in its favor on all of Plaintiffs' claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 12, 2019, I electronically filed the foregoing document, **Defendants' Brief in Support of Motion for Summary Judgment**, with the Clerk of the Court using the CM/ECF system, which provided electronic service upon all counsel of record.

/s/ Tinisha Brooks